

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

e application of: Gibbs et al.

erial No.:

10/761,886

Group No.: 1652

Filed:

January 20, 2004

Examiner:

Fronda, Christian L.

For:

NOVEL POLYPEPTIDES AND COAGULATION THERAPY

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN THREE MONTHS OF FILING OR BEFORE MAILING OF FIRST OFFICE ACTION (37 CFR 1.97 (b))

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited on the date shown below with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

(check and complete appropriate item below);

37 CFR 1.8 (a) x with sufficient postage as first class mail	<u>or</u>	37 CFR 1.10 as "Express Mail Post Office to Addressee" Mailing Label No.
Date: 17 MARCH 2005		Sharon A. Lira (Type or print name of person mailing paper) (Signature of person mailing paper)



The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97 (b).

Reg. No. 27, 043

Tel. No.: (650) 522-5546

SIGNATURE OF ATTORNEY

Max D. Hensley

Type or print name of attorney

Gilead Sciences, Inc. 333 Lakeside Drive

P.O. Address

Foster City, CA 94404



Attorney Docket No. 190:2D2 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re applica	tion of: Gibbs et al.		
Serial No.:	10/761,886	Group No.:	1652
Filed:	January 20, 2004	Examiner:	Fronda, Christian L.
For:	NOVEL POLYPEPTIDES A	ND COAGU	LATION THERAPY
P.O. Box 14	er for Patents		·
	INFORMATION DISC	CLOSURE	STATEMENT (modified)
List of Sect	ions Forming Part of This	nformation	Disclosure Statement.
The following	g sections are being submitte	ed for this In	formation Disclosure Statement:
1. X	Preliminary Statements		
2. X	FORM PTO - 1449 (Modified	1)	
3. X	Identification of Prior Applica	tion in Which	Listed Information Was Already Cited.
	CER	TIFICATE OF	MAILING
attached or e	nclosed) is being deposited on	the date show	ent (along with any paper referred to as being wn below with the United States Postal Service in P.O. Box 1450, Alexandria, VA 22313-1450.
	37 CFR 1.8 (a) ient postage as mail	<u>or</u>	as "Express Mail Post Office to Addressee" Mailing Label No.
Date:	7 MARCH 200	<u> </u>	Sharon A. Lira (Type or print pame of person mailing paper) (Signature of person mailing paper)

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose. To the extent that this submission includes an International Search Report, such Report is submitted to facilitate the Examiner's analysis of the references and not out of any belief that the International Searching Authority's construction of the relevance of the references has any bearing under United States Law.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 CFR 1.97 (g)), an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Section 3. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

This application relies, under 35 U.S.C. 120, at least on the earlier filing dates of prior applications:

Serial No.: 09/504,735 Serial No.: 08/338,368 US-6,110,721

Serial No.: 08/258,038

Serial No.: 08/152.657

Filed on: Filed on: February 16, 2000 November 14, 1994

Filed on: Filed on:

June 10, 1994 (abandoned) November 12, 1993 (abandoned)

Copies of references are not supplied to the extent that they are found in the file history of the prior application(s). Copies of references that were not supplied in the prior application(s), if any, accompany this paper.

Reg. No. 27, 043

Tel. No.: (650) 522-5546

SIGNATURE OF ATTORNEY

Max D. Hensley

Type or print name of attorney

Gilead Sciences, Inc. 333 Lakeside Drive

P.O. Address

Foster City, CA 94404

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT **BY APPLICANT**

(37 CFR 1.98(b))

Sheet 1 of 5 ATTY DOCKET NO.: 190.2D2 SERIAL NO.: 10/761,886

APPLICANT: Gibbs et al.

GROUP ART UNIT: 1652 FILING DATE: 1/20/04

EXAMINER NAME:

U.S. PATENT DOCUMENTS

Examiner initials	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
		4,303,592	12-01-1981	Laura et al	
		4,775,624	10-04-1988	Bang et al	
		4,849,403	07-18-1989	Stocker et al	
		4,959,314	09-25-1990	Mark et al	
		5,093,117	03-03-1992	Lawrence et al	
		5,116,943	05-26-1992	Koths et al	
		5,147,638	09-15-1992	Esmon et al	
		5,304,482	04-19-1994	Sambrook et al	
		5,338,546	08-16-1994	Bennett et al	
		5,352,664	10-04-1994	Carney et al	

FOREIGN PATENT DOCUMENTS

Examiner initials	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages Or Relevant Figures Appear	T
		0 512 011 B1	04-06-1994	IMMUNO Aktiengesellschaft		
		WO 93/09807	05-27-1993	The Scripps Research Institute		
		WO 93/15755	08-19-1993	SCHERING AKTIENGESELLSCHAFT		
		WO 93/24635	12-09-1993	Genentech, Inc.		

NON PATENT LITERATURE DOCUMENTS

		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium,catalog, etc.), date, page(s), volumn-issue number(s), publisher, city and/or country where published.	Т
		Alberts et al., "Most Mutations in Proteins Are Deleterious and Are Eliminated by Natural Selection", pp. 215, MOLECULAR BIOLOGY OF THE CELL, 1983	
Banfield et al, "Partial characterization of vertebrate prothrombin cDNAs: Amplification and		sequence analysis of the B chain of thrombin from nine different species", 89:2779-2783, PROC	

EXAMINER

DATE CONSIDERED

FORM PTO-1449	ATTY DOCKET NO.: 190.2D2	SERIAL NO.: 10/761,886
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	APPLICANT: Gibbs et al.	
INFORMATION DISCLOSURE STATEMENT	FILING DATE: 1/20/04	GROUP ART UNIT: 1652
BY APPLICANT	EXAMINER NAME:	

(37 CFR 1.98(b))

Sheet 2 of 5

Examiner initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium,catalog, etc.), date, page(s), volumn-issue number(s), publisher, city and/or country where published.	Т
Adhesion", 112(2):335-344, J CELL BIOL, 1991		Bar-Shavit et al, "An Arg-Gly-Asp Sequence Within Thrombin Promotes Endothelial Cell Adhesion", 112(2):335-344, J CELL BIOL, 1991	
		Bar-Shavit et al, "Localization of a Chemotactic Domain in Human Thrombin", 23(3):397-399, BIOCHEM, 1984	
		Bar-Shavit et al, "Identification of a thrombin sequence with growth factor activity on macrophages", 83:976-980, PROC NATL ACAD SCI, 1986	
		Barnhart, Marion I., "Immunochemistry", , BLOOD CLOTTING ENZYMOLOGY (W. H. Segers, Ed.), 1967	
		Baum, R., "Mutated Proteins Unlocking Secrets of How Native Proteins Function", 69:23-30, C&E NEWS, 1991	
		Baum, R. M., "Enzyme Chemistry Set To Advance As New Techniques Are Applied", pp. 7 - 14, C&E NEWS, 14-Jul-1986	
		Borowski et al, "Metal and Phospholipid Binding Properties of Partially Carboxylated Human Prothrombin Variants", 260(16):9258-9264, J BIOL CHEM, 1985	
		Borowski et al, "Distribution of Gamma-Carboxyglutamic Acid Residues in Partially Carboxylated Human Prothrombins", 261(4):1624-1628, J BIOL CHEM, 1986	
		Bowie et al, "", 247:1306-1310, SCIENCE, 1990	
		Carter et al, "Engineering Enzyme Specificity by Substrate-Assisted Catalysis", 237:394-399, SCIENCE, 1987	
		Chang, Jui-Yoa, "Deciphering the structural elements of hirudin C-terminal peptide that bind to the fibrinogen recognition site of alpha-thrombin", 30:6656-6661, BIOCHEM, 1991	
		Comp et al., "Activation of Protein C in Vivo", 70:127-134, J CLIN INVEST, 1982	
		Craik et al, "Redesigning Trypsin: Alteration of Substrate Specificity", 228:291-297, SCIENCE, 1985	
		Dang et al., "Rational engineering of activity and specificity in a serine protease", 15(2):146-149, NATURE BIOTECHNOLOGY, 1997	
		Degen et al, "Characterization of the Complementary Deoxyribonucleic Acid and Gene Coding for Human Prothrombin", 22:2087-2097, BIOCHEM, 1983	
		Ehrlich et al, "Recombinant Human Protein C Derivatives: Altered Response to Calcium Resulting in Enhanced Activation by Thrombin", 9(8):2367-2373, EMBO J, 1990	
		Esmon et al., "Inflammation and Coagulation: Linked Processes Potentially Regulated Through A Common Pathway Mediated by Protein C", 66(1):160-165, THROMB HAEMO, 1991	
		Estell et al, "Probing Steric and Hydrophobic Effects on Enzyme-Substrate Interactions by Protein Engineering", 233:659-663, SCIENCE, 1986	
		Estell et al, "Engineering an Enzyme by Site-directed Mutagenesis to Be Resistant to Chemical Oxidation", 260(11):6518-6521, J BIOL CHEM, 1985	
	-	Fenton II, et al, "Regulation of Thrombin Generation and Functions", 14(3):234-240, SEMINARS IN THROMBOSIS AND HEMOSTASIS, 1988	

EXAMINER

DATE CONSIDERED

FORM PTO-1449	ATTY DOCKET NO.: 190.2D2	SERIAL NO.: 10/761,886
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	APPLICANT: Gibbs et al.	
INFORMATION DISCLOSURE STATEMENT	FILING DATE: 1/20/04	GROUP ART UNIT: 1652
BY APPLICANT (37 CFR 1.98(b))	EXAMINER NAME:	
Sheet 3 of 5		

Examiner initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium,catalog, etc.), date, page(s), volumn-issue number(s), publisher, city and/or country where published.	Т
		Furie et al, "Computer-generated Models of Blood Coagulation Factor Xa, Factor IXa, and Thrombin Based upon Structural Homology with Other Serine Proteases", 257(7):3875-3882, J BIOL CHEM, 1982	
		Gan et al, "Characterization of the Heparin Binding Exosite of Thrombin", 69:1044, THROMB HAEMO, 1993	
		Gibbs et al, "Conversion of Thrombin into an Anticoagulant by Protein Engineering", 378:413-416, NATURE, 1995	
		Gibbs et al, "Functional Mapping of the Surface Residues of Human Thrombin", 82(10):206A, BLOOD, 1993	
		Grutter et al, "Crystal structure of the thrombinhirudin complex: a novel mode of serine protease inhibition", 9(8):2361-2365, EMBO J, 1990	
		Hanson et al, "Antithrombotic Effects of Thrombin-induced Activation of Endogenous Protein C in Primates", 92:2003-2012, J CLIN INVEST, 1993	
		Hedner et al, "Chapter 84: Introduction to Hemostasis and the Vitamin K-Dependent Coagulation Factors", pp. 2107-2373, THE METABOLIC BASIS OF INHERITED DISEASE II (6th Ed.), 1989	
		Hedstrom et al, "Converting Trypsin to Chymotrypsin: The Role of Surface Loops", 255:1249-1253, SCIENCE, 1992	
		Henriksen et al, "Identification of the Primary Structural Defect in the Dysthrombin Thrombin Quick I: Substitution of Cysteine for Arginine-382", 27:9160-9165, BIOCHEM, 1988	
		Henriksen et al, "Substitution of Valine for Glycine-558 in the Congenital Dysthrombin Thrombin Quick II Alters Primary Substrate Specificity", 28:2078-2082, BIOCHEM, 1989	
		Hofsteenge et al, "Enzymatic Properties of Proteolytic Derivatives of Human Alpha-Thrombin", 27:2144-2151, BIOCHEM, 1988	
		Hung et al, "Mirror Image Antagonists of Thrombin-induced Platelet Activation Based on Thrombin Receptor Structure", 89:444-450, J CLIN INVEST, 1992	
		Hyde et al., "Isolation and Characterization of an in vivo Thrombin-Induced Anticoagulant Activity", 13:121-128, SCAND. J. HAEMAT., 1974	
		Jorgensen et al, "Expression of Completely Gamma-Carboxylated Recombinant Human Prothrombin", 262(14):6729-6734, J BIOL CHEM, 1987	
		Le Bonniec et al, "The Role of Thrombin's Tyr-Pro-Pro-Trp motif in the Interaction with Fibrinogen, Thrombomodulin, Protein C, Antithrombin III, and the Kunitz Inhibitors", 268(25):19055-19061, J BIOL CHEM, 1993	
		Li et al, "Mutagenesis On The Loop Thr147 To Ser158 Of Human Thrombin Does Not Abolish Thrombomodulin Binding Site", 69:1045, THROMB HAEMO, 1993	
		Lundblad et al., "The reaction of bovine alpha-thrombin with tetranitromethane", 263(8):3729-3734, J BIOL CHEM, 1988	

EXAMINER

DATE CONSIDERED

FORM PTO-1449	ATTY DOCKET NO.: 190.2D2	SERIAL NO.: 10/761,886
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	APPLICANT: Gibbs et al.	
INFORMATION DISCLOSURE STATEMENT	FILING DATE: 1/20/04	GROUP ART UNIT: 1652
BY APPLICANT (37 CFR 1.98(b))	EXAMINER NAME:	
Sheet 4 of 5		

Examiner initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium,catalog, etc.), date, page(s), volumn-issue number(s), publisher, city and/or country where published.	Т
		MacGillivray et al, "Recombinant Genetic Approaches to Functional Mapping of Thrombin", 485:73-79, ANN NY ACAD SCI, 1986	
		Magnusson et al, "Complete Primary Structure of Prothrombin: Isolation, Structure and Reactivity of Ten Carboxylated Glutamic Acid Residues and Regulation of Prothrombin Activation by Thrombin", 2:123-149, PROT & BIOL CONTROL, 1975	•
		Mann et al, "Biochemistry of Thrombin", 2 ed., Chapter 10, pp. 148-161, HEMO THROMB, 1987	
		Mann et al, "The Molecular Weights of Bovine Thrombin and Its Primary Autolysis Products", 244(23):6555-6557, THROMB PEPT, 1969	
		Martin et al., "The structure of residues 7-16 of the A-alpha-chain of human fibrinogen bound to bovine thrombin at 2.3-angstroms resolution", 267(11):7911-7920, J BIOL CHEM, 1992	
		Meier, J. et al, "Snake Venom Protein C Activators", 5:265-279, Handbook of Natural Toxins, 1991	
		Miyata et al, "Prothrombin Tokushima, a Replacement of Arginine-418 by Tryptophan That Impairs the Fibrinogen Clotting Activity of Derived Thrombin Tokushima", 26:1117-1122, BIOCHEM, 1987	
		Miyata et al., "Prothrombin Salakta: substitution of glutamic acid-466 by alanine reduces the fibrinogen clotting activity and the esterase activity", 31:7457-7462, BIOCHEM, 1992	
		Nakagaki et al, "Isolation and Characterization of a Protein C Activator from Tropical Moccasin Venom", 58:593-602, THROMBOSIS RESEARCH, 1990	
0		Neurath, Hans, "Evolution of Proteolytic Enzymes", 224:350-357, SCIENCE, 1984	
		Ni et al., "High Resolution NMR Studies of Fibrinogen-like Peptides in Solution: Structural Basis for the Bleeding Disorder Caused by a Single Mutation of Gly(12) to Val(12) in the A alpha Chain of Human Fibrinogen Rouen", 28:3106-3119, BIOCHEMISTRY (2nd Ed.), 1989	
		Noe et al, "The Use of Sequence-specific Antibodies to Identify a Secondary Binding Site in Thrombin", 263(24):11729-11735, J BIOL CHEM, 1988	
		Paborsky et al., "The Single-Stranded DNA Aptamer-binding Site of Human Thrombin", 268(28):20808-20811, J BIOL CHEM, 1993	
		Padmanabhan et al, "The Structure of alpha-Thrombin Inhibited by a 15-Mer Single-stranded DNA Aptamer", 268(24):17651-16754, J BIOL CHEM, 1993	
		Rabiet et al, "Molecular Defect of Prothrombin Barcelona", 261(32):15045-15048, J BIOL CHEM, 1986	
		Richardson et al, "Enhancing protein C interaction with thrombin results in a clot-activated anticoagulant", 360:261-264, NATURE, 1992	
		Rosenberg et al, "Multiple Bovine Thrombin Components", 245(19):5049-5056, J BIOL CHEM, 1970	
-		Rydel et al, "The Structure of a Complex of Recombinant Hirudin and Human Alpha-Thrombin", 249:277-280, SCIENCE, 1990	

EXAMINER

DATE CONSIDERED

FORM PTO-1449	ATTY DOCKET NO.: 190.2D2	SERIAL NO.: 10/761,886
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	APPLICANT: Gibbs et al.	
INFORMATION DISCLOSURE STATEMENT	FILING DATE: 1/20/04	GROUP ART UNIT: 1652
BY APPLICANT CFR 1.98(b))	EXAMINER NAME:	
Sheet 5 of 5		

Examiner initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium,catalog, etc.), date, page(s), volumn-issue number(s), publisher, city and/or country where published.	T
		Seegers et al, "Preparation and Properties of Thrombin", 128:194-201, ARCH BIOCHEM & BIOPHYS, 1968	
		Sheehan et al, "Identification of the Heparin-Binding Exosite of Thrombin By Site-Directed Mutagenesis", 69:1044, THROMB HAEMO, 1993	
		Sheehan et al, "Molecular Mapping of the Heparin Binding Exosite of Thrombin", 82:206a, Abstract No. 809, BLOOD, 1993	
		Stocker et al, "Practical Application of the Protein C Activator Protac from Agkistrodon Contrortix Venom", 115(3,S):260-264, FOLIA HAEMATOL., LEIPZIG, 1988	
		Stocker et al, "Protein C Activators in Snake Venoms", 79:37 - 47, Behring Inst. Mitt., 1986	
		Strukova et al, "Anticoagulant Effect of the Protease from Agkistrodon Venom Mediated by Protein C Activation in Rats", 55(1):149-153, THROMBOSIS RESEARCH, 1989	
		Stryer et al., "Biochemistry", 3rd ed.,pp. 136-138, , 1988	
		Suzuki et al, "Localization of Thrombomodulin-binding Site within Human Thrombin", 265(22):13263-13267, J BIOL CHEM, 1990	
		Tsiang et al, "Equilibrium Binding of Thrombin to Recombinant Human Thrombomodulin: Effect of Hirudin, Fibrinogen, Factor Va, and Peptide Analogues", 29:10602-10612, BIOCHEM, 1990	
		Valenzuela et al, "Is sequence conservation in interferons due to selection for functional proteins", 313(21):698-700, NATURE, 1985	
		Wells et al, "Designing substrate specificity by protein engineering of electrostatic interactions", 84:1219-1223, PROC NATL ACAD SCI, 1987	
		White et al, "Structure-Function Relations in Platelet-Thrombin Reactions", 256(4):1763-1766, J BIOL CHEM, 1981	
		Ye et al, "Glycosaminoglycan contributions to both Protein C activation and thrombin inhibition involve a common arginini-rich site in thrombin", 269(8):17965-17970, J BIOL CHEM, 1994	

EXAMINER

DATE CONSIDERED